JAN - 5 2011

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Optasia Medical
THE SCIENCE OF IMAGE UNDERSTANDING

510(k) Summary

As required by 21 CFR 807.92(c)

Owner's Name

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Date this Summary was Prepared

November 17, 2010

Classification name

Classification name:	Picture archiving and communications system
Regulation:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Class:	II

Common/Usual Name

Spine Analysis Software

Proprietary Name

SpineAnalyzer

JAN - 5 2011

Establishment Registration Number

The SpineAnalyzer was manufactured by:

Optasia Medical Limited
Haw Bank House
High Street
Cheadle
Cheshire SK8 1AL
United Kingdom
Establishment Registration Number: "to be applied for"

Substantial Equivalence

Optasia Medical believes that its SpineAnalyzer is substantially equivalent in design, use and materials to the GE LUNAR Dual-energy Vertebral Assessment View Software, K023554.

Description of Product

The Optasia Medical SpineAnalyzer is a stand-alone software package which can be installed and used on any "personal computer" meeting the minimum specification requirements defined in Tab 16, section 16.6. SpineAnalyzer is designed with context sensitive menus to guide the qualified medical practitioner through the vertebral assessment workflow of lateral spine x-rays or DXA images from patients at risk of, or suffering from, osteoporosis.

The SpineAnalyzer allows visualization of the spine from lateral spine x-ray or DXA images, and hence identification of vertebral deformities. The SpineAnalyzer can then suggest points that represent the vertebral bodies in the image using a "6-point morphometry" protocol, for the vertebrae between T4 and L4. These points are then reviewed by a suitably qualified medical practitioner who can adjust them using his/her clinical expertise to produce an annotated digital image of the spine in the region of interest.

A set of "tools" are provided within the SpineAnalyzer software to allow the clinical specialist to annotate and measure features on the digital image of spine as "deformity percentages" which are derived from heights or ratios of heights of the vertebral bodies. Further tools are provided to allow the measurements to be reported; allowing the physician to compare these measurements against those made on previous occasions and hence infer

improvement or deterioration in the condition of the area of interest of the spine.

The Optasia Medical SpineAnalyzer guides the qualified medical practitioner's workflow in the objective assessment of the vertebrae T4 through L4 captured in the image. In osteoporosis, a vertebral deformity may indicate an osteoporotic fracture. A qualified medical practitioner can use the information provided by SpineAnalyzer, together with other clinical information, to make a diagnosis.

In patients who have been diagnosed with osteoporosis, a change in vertebral deformity over time may indicate an incident vertebral fracture. SpineAnalyzer facilitates the comparison of baseline and follow-up spine x-ray or DXA images which the qualified medical practitioner, together with other clinical information, can use to diagnose incident vertebral fracture.

The intended use of SpineAnalyzer™ is to facilitate the visual or quantitative assessment of vertebral body deformities in lateral DXA or digital/digitized X-ray images.

The indications for use are defined as:

- The Optasia Medical SpineAnalyzer™ is intended for the visualization or quantitative assessment of vertebral body deformities between levels T4 and L4 of the thoracic and lumbar spine in adult patients at risk of osteoporotic fracture. The qualified medical practitioner uses the device to calculate vertebral deformity ratios derived from the interactive placement of morphometry markers. Deformity grades are then calculated using criteria published by Genant[†]. Additionally, the qualified medical practitioner can record a manual Genant Semi-Quantitative score based on visual assessment.
- The qualified medical practitioner may use the deformity ratios and deformity grades to assist in the diagnosis of vertebral fracture and may, along with knowledge of patient history, apply medical expertise and best practice clinical judgment to determine if therapeutic intervention is indicated.

[†]Genant H K, et al. Vertebral Fracture Assessment Using a Semiquantitative Technique. Journal of Bone and Mineral Research. 8(9), pp1137-1148, 1993.

The Optasia Medical SpineAnalyzer will be delivered on a CD-ROM together with documentation containing operation manual, user installation instructions and release notes. The CD-ROM will auto-run an application installer and will contain the following files:

- An installer program which utilizes the "Windows Installer" on the target system.
- A separate PDF (Portable Document Format) document which contains user installation instructions and release notes.
- A separate PDF file containing the operation manual.
- Additional system files associated with auto-run installation.

The Optasia Medical SpineAnalyzer software does not contain any integrated "help" function. The user is guided through the workflow by a context-sensitive menu system available from a right-button mouse click at each stage.

Technological Comparison to Predicate Devices

The table below provides a comparison of the SpineAnalyzer device and the predicate device. These differences raise no new types of safety or effectiveness questions.

Feature	Optasia Medical SpineAnalyzer	GE Lunar Dual-energy Vertebral Assessment View Software K023554
Minimum Specification (Hardware)	Pentium IV-class processor with 1 GB RAM 1024 x 768 color display resolution	Greater than 900Mhz Pentium 512 MB RAM Greater than 10GB hard disk 17" SVGA monitor (1024x768x32-bit color) ZIP 250 drive CD ROM Audio capable with speakers Modem Fast Serial I/O board (GE MEDICAL SYSTEMS part number 7151) - Prodigy only
Platform Software Requirements	Windows XP Professional with SP2 .NET Framework 2.0 PDF Reader	Windows® XP Professional operating system Internet Explorer version 5.0
Image Retrieval	Can load images from DICOM files and in TIFF format	Works only with images generated on GE Lunar scanners.
Image Manipulation	Basic manipulations supported are brightness, contrast, histogram equalization, invert, pan, zoom	Basic manipulations supported are brightness, contrast, clearview (edge enhancement), pan, zoom
Image Annotation	Software overlays relevant annotation data for clinician review, including vertebral outlines, 6-point morphometry markers and height markers	Software overlays relevant annotation data for clinician review, including vertebral outlines and 6-point morphometry markers. Heights are calculated but not annotated on the image
Patient contact & control of life sustaining devices	No contact or control	No contact or control
Image Interpretation	Manual by Clinician, captured as free text "Impression" narrative on report	Manual by Clinician, captured as free text "Comments" narrative on report

Feature	Optasia Medical SpineAnalyzer	GE Lunar Dual-energy Vertebral Assessment View Software K023554
Target Anatomy	Spine (Lateral) T4-L4	Spine (Lateral & AP) T4-L4
Modality	DXA, and digital or digitized X-ray	DXA, SXA
Label Vertebral Levels	Clinician manually labels vertebra	Clinician manually labels vertebra
Automated annotation	Physician clicks approximate center of vertebrae of interest; software returns suggested vertebral body contour and 6-point morphometry placements	Physician clicks approximate center of vertebrae of interest; software returns suggested vertebral body contour and 6-point morphometry placements
Vertebral Body Contour Display	95-point, full contour capturing endplate projections, anterior and posterior extent of vertebral body. Used to suggest 6-point placements. Displayed but not shown on the report.	Vertebra "ROI" (region of interest) defined by region enclosed by vertebral "bone edges". Displayed and shown on the report
Vertebral Body Contour Placement	Clinician interactively adjusts contour components; suggested 6-point placements updated accordingly (unless 6-point placements have been directly edited)	Clinician interactively adjusts contour by moving 6-points
6-pt Morphometry Placement	Initial placement derived from contour. Clinician manually adjusts point placements	Initial placement derived from contour. Clinician manually adjusts point placements
Vertebral Heights (anterior, mid and posterior)	Device computes heights from morphometry points (in pixels).	Device computes heights from morphometry points (in cm).
Height ratio: Wedge	Device calculates Ha/Hp, which is same as method 2 in Black95[1]. Reported as deformity percentage (see below)	Device calculates Ha/Hp, which is same as method 2 in Black95. Reported as deformity ratio percentage (see below)
Height ratio: Biconcavity	Device calculates Hm/Hp, which is same as method 2 in Black95 paper. Reported as deformity percentage (see below)	Device calculates Hm/Hp, which is same as method 2 in Black95 paper. Reported as deformity ratio percentage (see below)
Height ratio: Crush	Device calculates ratio according to method 2 of Black95 paper. See labeling comparison below for algorithmic details. Reported as deformity percentage (see below)	Device calculates ratio of vertebral posterior height to average height of L2-L4 vertebrae in same image. Reported as deformity percentage (see below)
Deformity Percentage	Calculated as 1-height ratio and expressed as percentage, as in Genant93[2] paper e.g. a ratio of 0.75 is a 25% deformity	Calculated as height ratio and expressed as percentage e.g. a ratio of 0.75 is a 75% deformity ratio
Deformity Grade	Calculated from deformity percentages using the Genant height reduction thresholds i.e. normal <20%, mild <25%, moderate <40%, severe >=40%. Thresholds cannot be altered	Calculated from deformity percentages using Z-scores (number of SDs from mean of normative data) i.e. normal <2sd, mild <3sd, moderate <4sd, severe >=4sd. Thresholds cannot be altered.
Deformity Grade Color	Deformity grades are color-coded based upon their values, to draw the eye. Mild – yellow, moderate – orange, severe – red.	Deformity grades are color-coded based upon their values, to draw the eye. Mild – white, moderate – half-red/half-white, severe – red.

[1] Black D M, Palermo L, Nevitt M C, Genant H K, Epstein R, San Valentin R, Cummings S R. Comparison of methods for defining prevalent vertebral deformities: the Study of Osteoporotic Fractures. J Bone Miner Res. 10(6): 890-902. 1995.

[2] Genant H K, et al. Vertebral Fracture Assessment Using a Semiquantitative Technique. Journal of Bone and Mineral Research. 8(9): 1137-1148. 1993.

Feature	Optasia Medical SpineAnalyzer	GE Lunar Dual-energy Vertebral Assessment View Software K023554
Genant SQ score	Device allows clinician to capture manual score of mild, moderate or severe wedge, biconcave or crush deformity, or explicitly score vertebra as normal. Manual score is recorded separately from score derived from quantitative morphometry.	Device allows clinician to capture manual score of mild, moderate or severe wedge, biconcave or crush deformity, or implicitly score vertebra as normal. Manual score replaces score derived from quantitative morphometry.
Report generation	Yes – includes annotated images, deformity percentages, deformity classifications and manual Genant SQ scores	Yes – includes annotated images, deformity percentages, deformity classifications or manual Genant SQ scores

Performance Testing

No performance data (laboratory, animal or clinical) is included.

Conclusion

Optasia Medical believes the SpineAnalyzer is substantially equivalent to the predicate device on the basis of intended use and technological characteristics. Further that the descriptive characteristics contained in the PreMarket Notification are sufficient to assess equivalence without comparison of performance data (laboratory, animal or clinical).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Anthony Holmes
Vice President of Technical Services
Optasia Medical
Haw Bank House, High Street
Cheadle, Cheshire, SK8 1AL
UNITED KINGDOM

JAN - 5 2011

Re: K103475
Trade/Device Name: SpineAnalyzer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: November 17, 2010
Received: November 24, 2010

Dear Mr. Holmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103475 JAN - 5 2011

Device Name: SpineAnalyzer JAN - 5 20..

Indications for Use:

The Optasia Medical SpineAnalyzer™ is intended for the visualization or quantitative assessment of vertebral body deformities between levels T4 and L4 of the thoracic and lumbar spine in adult patients at risk of osteoporotic fracture. The qualified medical practitioner uses the device to calculate vertebral deformity ratios derived from the interactive placement of morphometry markers. Deformity grades are then calculated using criteria published by Genant[†]. Additionally, the qualified medical practitioner can record a manual Genant Semi-Quantitative score based on visual assessment.

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[†]Genant H K, et al. Vertebral Fracture Assessment Using a Semiquantitative Technique. Journal of Bone and Mineral Research. 8(9), pp1137-1148, 1993.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003) Mark D O'Kane

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K103475